

12130245

5. 510(K) SUMMARY

February 8, 2013

MAR 01 2013

Owner:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Contact Person:

Nanette Hedden
Associate Director, Global Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073
Telephone: (224) 270-4871
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Device name:

Stopcock and I.V. Solution Administration Sets with Stopcocks

Table 5-1.
Representative Product Codes for Stopcock and I.V. Solution Administration Sets with Stopcocks

Code number	Name
2C6204	Large Bore Stopcock with Rotating Male Luer Lock
STP5604	Large Bore Stopcock with Extension Set
2C6218	Three Gang Large Bore Stopcock Manifold
2C6255	Clearlink System Continu-Flo Solution Set Large Bore Stopcock Extension Set
2C6607	Interlink System Extension Set Large Bore Stopcock with Rotating Male Luer Lock
STP0142	Interlink System Continu-Flo Solution Set Large Bore Stopcock Manifold Large Bore Stopcock with Rotating Male Luer Lock Extension Set

Common name:

Stopcock and I.V. Solution Administration Sets with Stopcocks

Classification name:

IV Administration Set (21 CFR 880.5440, Product Code FMG, FPA)

Predicate Device :

**Table 5-2:
Previous 510(k)s**

Device	Company	Previous 510(k)	Clearance date
Stopcock Manifold Gangs	Baxter Healthcare Corp.	K962581	August 28, 1996
Continu-Flo Solution Set/Secondary Medication Set	Baxter Healthcare Corp.	K961225	June 21, 1996

Device Description:

The proposed devices, which are the subject of this Special 510(k) Premarket Notification, consist of a stand-alone stopcock, stopcock manifold gangs, Intravenous (I.V.) administration sets with stopcock(s), and I.V. extension sets with stopcock(s). They are single use disposable devices intended for use for continuous or intermittent fluid administration or withdrawal of fluids. These devices are the same as the current marketed devices, previously cleared under 510(k) premarket notifications K962581 (cleared August 28, 1996), K961225 (cleared June 21, 1996) and K022895 (Elcam Plastic, cleared October 18, 2002).

The stand-alone stopcock is an in-line access site and can be connected to male Luer adapters (e.g., syringes or sets) to allow needleless access to the fluid or vascular path. It is used to control the fluid flow pathway by rotating the flow control handle.

The stopcock manifold gangs consist of individual stopcocks assembled in series through common Luer fittings to form a manifold or gang. These pre-assembled stopcock gangs provide multiple access sites into a common fluid path for the administration of drugs and solutions. The Luer connectors on either end of the stopcock gang allow connection to an administration or extension set for fluid administration through an indwelling intravascular catheter.

The I.V. administration sets with stopcock(s) (i.e. solution sets, secondary medication sets, Continu-Flo sets) are used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. They contain the stopcock(s) that can be used for the administration of secondary medication.

The I.V. extension sets with stopcock(s) are used for the administration and withdrawal of fluids. They consist of the stopcock connected to the extension set.

Currently, Baxter uses three stopcock designs in the stopcock system. The basis for this premarket notification is the standardization to one stopcock design. No new materials of construction are being introduced into Baxter's stopcock system as part of this change. This change does not impact the intended use or the fundamental scientific technology of the device. The product labels are also being updated to add the indications for use statement of the device and clarify their use to comply with Baxter's labeling standards.

Statement of Intended Use:

To administer fluids from a container into the patient's vascular system through a vascular access device.

Technological Characteristics and Substantial Equivalence:

The proposed devices are equivalent to Baxter's currently legally marketed Stopcock Manifold Gangs cleared August 28, 1996 (K962581) and Continu-Flo Solution Set/Secondary Medication Set cleared June 21, 1996 (K961225). See Table 5-2. This modification will standardize the stopcock design to one design. The intended use, basic design and function and the materials for the proposed devices are equivalent to the predicate device.

Discussion of NonClinical Tests:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria and support that the devices are appropriately designed for the intended use. The following bench tests were conducted to evaluate the effect of the design modification on the functional performance of the Stopcock and I.V. Solution Administration Sets with Stopcock(s):

- Visual inspection
 - Inner diameter assessment
 - High pressure test
 - Long duration pressure test
 - ISO Luer tests on female and male Luer lock connectors
 - Plug torque test
 - Lipid resistance test
 - Rigid bond flex test
 - Rigid bond water pressure test
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- Rigid bond air pressure test
 - Rigid bond torque test
 - Tubing bond pressure test
 - Tubing bond tensile test

Conclusion:

The proposed devices are substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Ms. Nanette Hedden
Associate Director, Global Regulatory Affairs
Baxter Healthcare Corporation
32650 North Wilson Road
ROUND LAKE IL 60073

Re: K130245

Trade/Device Name: Stopcock and I.V. Solution Administration Sets with Stopcocks
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG, FPA
Dated: January 25, 2013
Received: January 31, 2013

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", written over a stylized graphic of the FDA logo.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130245

Device Name: SR

Stopcock and I.V. Solution Administration Sets with Stopcocks

Indications for Use:

To administer fluids from a container into the patient's vascular system through a vascular access device.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed  Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Sajjad H. Syed,
0.9.2342.19200300.100.1.1=2000601742
Date: 2013.02.28 11:02:12 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130245